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10/502,237	07/22/2004	Christian Duraffourd	P/24-182	1897

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NEW YORK, NY 100368403

EXAMINER

LIN, JERRY

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/502,237

Applicant(s)

DURAFFOURD ET AL.

Examiner

Jerry Lin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-18 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1 page (7/22/04)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 2, claims 8-12 and the species of J6 (a so-called growth index, which the ratio is a bone isoenzymes of the alkaline phosphatases/osteocalcin) where no optional substance is measured in the reply filed on February 22, 2007 is acknowledged.
2. However, newly submitted claims 14 and 15 are directed to an invention that is independent or distinct from the elected invention for the following reasons: Instant claims 14 and 15 each require a different set of indexes. Instant claim 14 requires at least two indexes. Instant claim 15 requires at least eight indexes. In contrast, the elected species only requires index J6. Since each of the claims and the elected species require a different set of indexes, each claim and the elected species would require its own set of measurements and would have its own unique special technical feature. Furthermore, each claim and the elected species would have a unique and distinct outcome. Since each claim and the elected species would have it own special technical feature, and they do not relate to a single general inventive concept.

Accordingly, claims 14-15 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of the Claims

Claims 1-7 are cancelled (drawn to an unelected group)

Claims 8-13 and 16-18 are under examination (specie J6 is elected in claim 8).

Claims 13-17 are withdrawn as being drawn to unelected species.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-13 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Instant claim 8, in step A, recites that the computer code performs measuring, in blood, a set of substances. However, the step also recites that the substances and parameters have already been measured in the blood. The step also recites "at least one index." It is unclear if the computer code is measuring blood components, or if the blood components have been measured previously, or if the computer code is measuring indexes. Clarification via clearer claim language is requested. For purposes of this action, the Examiner will interpret the claim to mean that the computer is

Art Unit: 1631

measuring indexes and the substances and parameters have already been measured.

Claims 9-13 and 16-18 are also rejected for depending from claim 8.

7. Also regarding instant claim 8, the claim recites, "which is a ratio of bone isoenzymes of the alkaline phosphatases/ osteocalcin" in reference to index J6. It is unclear if the ratio is referring to the ratio of alkaline phosphatases to osteocalcin or if the ratio is referring to the ratio of isoenzymes of alkaline phosphatases, and osteocalcin is measured separately. For purposes of this office action, the latter interpretation will be used.

8. Instant claim 9 in part A, recites in "on the one hand" and "on the other hand". It is unclear if these phrases are meant to present the patient's name or code, age, and sex as an alternative to "any known treatment" or the if the limitations are not presented in the alternative. For purposes of this action, the Examiner will interpret the claim to mean that the limitations are not presented in the alternative. Clarification via clearer claim language is requested.

9. Instant claim 9 also includes several lower case roman numerals in parenthesis. It is unclear what these roman numerals are labeling or representing.

10. Instant claim 10 is also unclear. The instant claim appears to be attempting to define "each median value", however the median value is never defined. Clarification via clearer claim language is requested.

11. Instant claim 13 is also unclear. The instant claim recites that one abnormality is looked for in the indexes of J1 to J157. One interpretation is that all of the indexes are considered. Another interpretation is that only one index is considered. For purposes

Art Unit: 1631

of this Examination, the latter interpretation will be used and the index that is considered is J6.

12. Instant claim 16 is unclear because the instant claim recites "a portion of indexes." One interpretation is that multiple indexes are required in the claim. Another interpretation is that "a portion" may refer to one or more indexes. For purposes of this Examination, the latter interpretation will be used.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claims 8-13 and 16-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

15. The instant claims are drawn to a software product. A software product may merely be a computer code, which is a list of instructions. A list of instructions is not a process, machine, manufacture, or composition of matter. Thus the instant claims are non-statutory.

16. Furthermore, the instant claims are drawn to a software product using a judicial exception of a mathematical algorithm. A judicial exception is non-statutory unless the claims include a step of physical transformation, or if the claims include a useful, tangible and concrete result. It is important to note, that the claims themselves must include a physical transformation step or an useful, tangible and concrete result in order for the claimed invention to be statutory. It is not sufficient that a physical

Art Unit: 1631

transformation step or a useful, tangible, and concrete result be asserted in the specification for the claims to be statutory. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, tangible, and concrete result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not include a tangible result. A tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claims end with the step of comparing indexes. However, this final step does not indicate that a result necessarily occurs. It only indicates a final processing step. Since, the instant claims do not necessarily conclude with a final result, the instant claims do not necessarily have a tangible result. Thus the instant claims do not include a tangible result. This rejection could be overcome by amendment of the claims to recite that a result of the method is

Art Unit: 1631

outputted to a display or a memory or another computer on a network, or to a user, or by including a physical transformation.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 8, 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magnusson et al. (Clinical Chemistry (1998) Volume 44, Number 8, pages 1621-1628) in view of Oremek et al. (Clinical Chemistry (1996) Volume 42, Number 5, pages 691-695) in view of Klotz et al. (The Journal of Urology (1999) Volume 161, pages 169-172) in view of Angelsen et al. (The Prostate (1997) Volume 31, pages 110-117) in view of Ganser et al. (Blood (1990) Volume 74, Number 4, pages 666-676).

The instant claims are drawn to a software product with computer code to measure the index of J6, which is the measurement of osteocalcin and the ratio of bone isoenzymes of alkaline phosphatases, using the data from measuring red blood cells, leukocytes, hemoglobin, neutrophils, eosinophils, lymphocytes, monocytes, platelets, lactate dehydrogenase, creatine phosphokinase, thyroid-stimulating hormone, alkaline phosphatases, liver or bone or intestine isoenzymes, osteocalcin, potassium, and calcium in blood previously taken from a patient, and where the computer code compares the index of J6 with the corresponding result from a healthy human being.

Regarding claims 8, 13 and 18, Magnusson et al. teaches a software product that takes data from measuring alkaline phosphatases, bone isoenzymes, and osteocalcin (page 1622, right column – 1624); determining the ratio of bone isoenzymes of the alkaline phosphatases (page 1624, left column, Table 1); measuring osteocalcin (page 1624, left column, Table 1); and comparing the indexes to the results from healthy human beings (page 1624, left column, Table 1), where the results from healthy human beings are median values (page 1624, left column, Table 1). Furthermore, Magnusson et al. accomplished their method using a software product (page 1623, right column).

Regarding 16 and 17, Magnusson et al. teach measuring an index using a score of functions involved in cancer (page 1624, paragraph bridging right and left column).

However, Magnusson et al. do not teach measuring red blood cells, leukocytes, hemoglobin, neutrophils, eosinophils, lymphocytes, monocytes, platelets, lactate dehydrogenase, creatine phosphokinase, thyroid-stimulating hormone, potassium and calcium.

Regarding claim 8, Oremek et al. teach measuring lactate dehydrogenase, potassium and calcium (page 169, right column, bottom) to determine if an individual is healthy.

However, Magnusson et al. and Oremek et al. do not teach measuring red blood cells, leukocytes, hemoglobin, neutrophils, eosinophils, lymphocytes, monocytes, platelets, creatine phosphokinase, and thyroid-stimulating hormone.

Regarding claim 8, Klotz et al. teach measuring creatine phosphokinase (page 170, right column, bottom paragraph) in association with prostate cancer.

However, Magnusson et al., Oremek et al., and Klotz et al. do not teach measuring red blood cells, leukocytes, hemoglobin, neutrophils, eosinophils, lymphocytes, monocytes, platelets, and thyroid-stimulating hormone.

Regarding claim 8, Angelsen et al. teach measuring thyroid-stimulating hormone (page 113, left column) in association with prostate cancer.

However, Magnusson et al., Oremek et al., Klotz et al., and Angelsen et al. do not teach measuring red blood cells, leukocytes, hemoglobin, neutrophils, eosinophils, lymphocytes, monocytes, and platelets.

Regarding claim 8, Ganzer et al. do teach measuring red blood cells, leukocytes, hemoglobin, neutrophils, eosinophils, lymphocytes, monocytes, and platelets (page 667 – 668).

It would have been obvious for one of ordinary skill in the art at the time of the invention to combine the modify Magnusson et al.'s method to include the various tests taught by Oremek et al., Klotz et al., Angelsen et al., and Ganzer et al. to gain the

Art Unit: 1631

benefit of being able to tests for different markers of the stages of prostate cancer.

Each of the instant references teach different markers for different stages of treated or untreated prostate cancer. Angelsen et al. teach that prostatic carcinomas are composed of a heterogeneous population of cells (page 110, left column). This would indicate that prostate cancer would have several different markers (page 111, left column). Thus, one of ordinary skill in the art would be motivated to look at the markers taught by the instant references in order to determine the stage or presence of prostate cancer and use these markers in the method taught by Magnusson et al.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JL

John S. Brusca 27 April 2007
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PRIMARY EXAMINER